

Appl. No. 10/601,596
Amendment dated: January 6, 2006
Reply to OA of: October 6, 2005

REMARKS

This is in response to the Official Action of October 6, 2005, in connection with the above-identified application.

Applicants have canceled claim 7 as being drawn to a non-elected species. Applicants reserve the right to file one or more divisional applications on the non-elected species at a later time.

The rejection of claims 1, 3-6 and 13 under 35 U.S.C. §102(e) as being anticipated by Prausnitz has been carefully considered but is most respectfully traversed in light of the following comments.

Applicants wish to direct the Examiner's attention to MPEP § 2131 which states that to anticipate a claim, the reference must teach every element of the claim.

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as is contained in the ... claim." *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). The elements must be arranged as required by the claim, but this is not an *ipsissimis verbis* test, i.e., identity of terminology is not required. *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (Fed. Cir. 1990).

The Official Action urges that Prausnitz discloses every element of the presently claimed invention, including a clutching mechanism comprising at least one elastic layer (as illustrated in Figures 11A and 11B), at least two protrusions each having a cylinder shape (presumably microneedles 116 illustrated in Figures 10A and 10B), a support mechanism (presumably inner cylinder 134 illustrated in Figure 13B) and a driving mechanism to deform a the layer (i.e., a vacuum pump as described at col. 13, lines 32-51). Applicants traverse this statement on numerous grounds.

First, the Official Action cites Figures 11A and 11B in support of the assertion that Prausnitz discloses at least one elastic layer. However, a careful reading of the portion of Prausnitz that describes Figures 11A and 11B reveals that the needles shown in Figures 11A and 11B are attached to rigid substrates which form a curved rather than a planar surface (see, e.g., col. 11, lines 23-25). That is to say, Figures 11A and 11B do not show an elastic layer as asserted in the Official Action, but rather show a stiff, non-flexible substrate that is formed in a hemispherical or elliptical shape in order to improve uniformity of penetration among the microneedles of an array. To the contrary, the present application clearly claims at least one elastic layer with at least two protrusions erected on the lower surface of the elastic layer. As explained in detail in the specification (see, e.g., page 7, lines 8-22 and Figures 2 and 3), the layer on which the micro pins are erected is flexible such that when gas is extracted from the supporting mechanism, the flexible layer is sunken into the supporting mechanism and the micro pins are tilted towards the center of the flexible layer. This movement of the pins allows the micro pins to clutch micro or nano objects and is only possible because of the flexible layer. Therefore, because Figures 11A and 11B clearly fail to disclose a flexible layer as claimed in the present invention, it is apparent that Prausnitz fails to disclose every element of the of the presently claimed invention and cannot properly support a §102 rejection according to the guidelines set forth in MPEP §2131. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Official Action also urges that Prausnitz discloses a vacuum pump driving mechanism to deform the elastic layer, and cites col. 13, lines 32-51 in support of this contention. Lines 32-51 of col. 13 describe in detail the microneedle device illustrated in Figure 13A. Specifically, this portion of Prausnitz discloses that the outer chamber 128 can be evacuated so that, when triggered, the skin at the site of administration is exposed to the vacuum and is pulled up into the device. That is to say, the substrate 122 does not move, but rather the skin over which the device is pulled up to the device. This is also clearly illustrated in Figure 13B. In Figure 13B, suction is not applied to the substrate 138 through the inner cylinder 134, but rather suction is applied to the skin via

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the outer cylinder 132. Optional pressure is applied to the inner cylinder 134 in order to facilitate flow of the drug in reservoir 136 into the microneedles, but no vacuum pump is used to draw a flexible layer inward. Therefore, this portion of Prausnitz clearly does not show a driving mechanism deforming the elastic layer in a way that the deformable area is sunken inwardly as claimed in the present application. Because Prausnitz fails to disclose this element of the presently claimed invention, the reference is clearly incapable of properly supporting a §102 rejection according to the guidelines set forth in MPEP §2131. Accordingly, Applicants respectfully request that this rejection be withdrawn.

The Official Action also ignores several limitations of presently claimed invention. Most notably, the Official Action fails to set forth where Prausnitz discloses tips of each protrusion defining a clutching point as recited in the present claims. The absence of such a disclosure is most evident in the fact that the device disclosed in Prausnitz is not for clutching micro or nano devices, but rather, is for transport of therapeutic or biological molecules across tissue barriers, such as human skin. A careful reading of Prausnitz reveals that no portion of the reference disclose using the microneedles for clutching or gripping as claimed in the present invention. The microneedles disclosed in Prausnitz are solely designed for being inserted into skin and to aid in delivering drugs or sampling biological fluids. Therefore, because the device disclosed in Prausnitz is designed for injection and is incapable of performing a clutching operation, it follows that Prausnitz fails to disclose tips of each protrusion defining a clutching point as recited in the present claims. Accordingly, Prausnitz is not capable of properly supporting a §102 rejection according to the guidelines set forth in MPEP §2131 and Applicants therefore request that the rejection be withdrawn.

The rejection of claim 2 under 35 U.S.C. §103(a) as being unpatentable over Prausnitz in view of Regan has been carefully considered but is most respectfully traversed in light of the following comments.

Applicants wish to direct the Examiner's attention to the basic requirements of a prima facie case of obviousness as set forth in the MPEP § 2143. This section states

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that to establish a prima facie case of obviousness, three basic criteria first must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine the reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.

The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, not in applicant's disclosure. In re Vaeck, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Section 2143.03 states that all claim limitations must be taught or suggested by the prior art. In re Royka, 490 F.2d 981, 180 USPQ 580 (CCPA 1974). "All words in a claim must be considered in judging the patentability of that claim against the prior art." In re Wilson, 424 F.2d 1382, 1385, 165 USPQ 494, 496 (CCPA 1970). If an independent claim is nonobvious under 35 U.S.C. 103, then any claim depending therefrom is nonobvious. In re Fine, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988).

Applicants also most respectfully direct the Examiner's attention to MPEP § 2144.08 (page 2100-114) wherein it is stated that Office personnel should consider all rebuttal argument and evidence presented by applicant and the citation of In re Soni for error in not considering evidence presented in the specification.

The Official Action rejects claim 2 as being unpatentable over Prausnitz (as applied to claim 1 on page 3 of the Official Action) in view of Regan. However, as discussed in detail above, Prausnitz fails to disclose several features of the claimed invention. Furthermore, Regan clearly fails to remedy the deficiencies identified above, as Regan merely discloses a device for assaying analytes in a fluid sample. Therefore, because neither Prausnitz nor Regan, either standing alone or in combination, disclose or suggest every element of the presently recited claims, Applicants respectfully request that this rejection be withdrawn.

Finally, Applicants note the objection to the specification for failing to provide a title of the invention that is descriptive. As stated in MPEP §606, the title should be brief

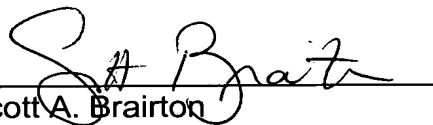
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but technically accurate and descriptive and should contain fewer than 500 characters. Applicants respectfully assert that the title "Micro/Nano Clutching Mechanism" is brief, accurate, descriptive and contains fewer than 500 characters, and therefore meets all of the criteria set forth in MPEP §606. In the event that the Examiner still believes that the title is not descriptive, Applicants respectfully solicit a suggestion by the Examiner of a title that would be deemed descriptive.

In view of the above comments, favorable reconsideration and allowance of all of the claims now present in the application are most respectfully requested.

Respectfully submitted,

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